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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ERIC B. STENZEL

Appeal 2008-1414
Application 10/701,455
Technology Center 3700

Decided: May 28, 2008

Before, TONI R. SCHEINER, DEMETRA J. MILLS, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

Claim 1 is representative.

1. A medical device for implantation in a body comprising:
a structure;
a set of first coated pellets, each of said first coated pellets containing

at least one first therapeutic composition, the set of first coated pellets deposited on the structure at a first site for controlled delivery of the at least one first therapeutic composition to a desired location within the body; and

a set of second coated pellets, each of said second coated pellets containing at least one second therapeutic composition, the set of second coated pellets deposited on the structure at a second site for controlled delivery of the at least one second therapeutic composition to a desired location within the body;

wherein each of said first coated pellets is covered with a first coating and each of said second coated pellets is covered with a second coating; wherein the first coating is thinner than the second coating and has a faster in vivo decomposition rate relative to the second coating to release the first therapeutic composition from the first site faster than the second therapeutic composition from the second site; and

wherein each of said first coated pellets contains a substance in addition to the first therapeutic composition such that each of the first coated pellets is substantially the same size as each of said second coated pellets.

4. The medical device of claim 1, further comprising an adhesive interposed between the first coated pellets and the structure.

Cited References

Bennett	US 6,339,130 B1	Jan. 15, 2002
Stoll	US 6,849,089 B2	Feb. 1, 2005

Grounds of Rejection

1. Claims 1, 4, 9-10, 12-16, and 24-27 stand rejected under 35 U.S.C. § 103(a) as obvious over Stoll.

2. Claims 5, 11, 17, and 19-23 stand rejected under 35 U.S.C. § 103(a) as obvious over Stoll in view of Bennett.

DISCUSSION

Background

The present invention relates to a "medical device for insertion or implantation in a body [which] includes a structure and at least one therapeutic composition deposited on the structure. The structure can include a first and a second site with therapeutic composition(s) deposited on each site. The therapeutic composition at the first site can be covered with a first protective layer and the therapeutic composition at the second site can be covered with a second protective layer such that the first protective layer, provides a faster *in vivo* decomposition rate relative to the second protective layer, thus enabling the release of the therapeutic composition from the first site at a faster rate than the release rate of the therapeutic composition from the second site." (Spec. 4.)

"[E]ach site can have the form of a micro coated pellet (or coated pellets) with each coated pellet including at least one active substance. … The coated pellets can be similar or dissimilar in composition, size, release rate or decomposition rate." (Spec. 4.)

"In … another embodiment, the invention comprises a stent having deposited thereon a plurality of pellets having one or more coating layers that act as a protective layer." (Spec. 4.)

DISCUSSION

1. Claims 1, 4, 9-10, 12-16, and 24-27 stand rejected under 35 U.S.C. § 103(a) as obvious over Stoll.

Claim interpretation

Appellant claims first coated pellets and second coated pellets, "wherein each of said first coated pellets contains a substance in addition to the first therapeutic composition such that each of the first coated pellets is substantially the same size as each of said second coated pellets." (Claim 1.)

In proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification, and claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art. *In re Sneed*, 710 F.2d 1544, 1548 (Fed. Cir. 1983).

Figure 3(A-D) of the Specification shows a drug mixture 301 and a micro coating layer 302 which are described as being embodiments of the micro coated pellets, as claimed. (Spec. 10, ¶30.) Because claim 1 requires that both the first and second pellets be coated, and requires that each of the first coated pellets is substantially the same size as each of said second coated pellets, we interpret the claims as requiring the first coated pellets and the second coated pellets, including the coating, to be substantially the same size, as depicted in Figure 3.

The Examiner finds that

> Stoll discloses the invention as claimed … comprising: A medical structure (2); a set of first coated pellets (the pellet is the internal structure 4" and the coating is the thin surrounding) each of the first coated pellets containing at least one first therapeutic composition, the set of first coated pellets deposited on the structure at a first site for controlled delivery of at least one first therapeutic composition; and a set of second coated pellets, (the second set of pellets can be interpreted as the internal pellet 4" with the thick outer diameter coating **adjacent**

> pellets 4" with the thin coating as seen in figure 7) each of the second coated pellets containing at least one second therapeutic composition (the second therapeutic composition is contained in the micro-sphere in a separate second compartment; the set of second coated pellets deposited on the structure at a second site for controlled delivery of the at least one second therapeutic composition to a desired location within the body; wherein each of said first coated pellets is covered with a first coating (the thin coating) and each of said second coated pellets is covered with a second coating (the thick coating); wherein the first coating is thinner than the second coating and has a faster in vivo decomposition rate relative to the second coating to release the first therapeutic composition from the first site faster than the second therapeutic composition from the second site (see col. 13, lines 18-29 and col. 4, lines 1-27); wherein each of the first coated pellets contains a substance in addition to the first therapeutic (see col. 12, lines that states that a "matrix" of a polymer and particles of cell proliferation-inhibiting substance may be used therefore the additional substance is the matrix blend).

(Ans. 3-4.)

As set forth above, the Examiner concludes that, in the case of the first and second coated pellets shown in Figure 7 of Stoll, the pellet is the internal structure 4" and the coating is the thin surrounding. (Ans. 4.)

Appellant contends that:

> None of the cited references discloses or suggests having pellets with different thicknesses but with additional substances as claimed to achieve "substantially the same size." In the Stoll '089 embodiment of Figure 7, the microcapsules have different coating thicknesses but **different** sizes.

(App. Br. 23.)

The issue before us is whether Stoll discloses first coated pellets and second coated pellets, wherein each of said first coated pellets contains a substance in addition to the first therapeutic composition such that "*each of the first coated pellets is substantially the same size as each of said second coated pellets*."

As discussed herein, we interpret the claims as requiring that the entire pellet, including its coatings, to be substantially the same size. Thus, we do not agree with the Examiner's conclusion that the pellet of Stoll is limited to the internal structure 4" and the coating is the thin surrounding. (Ans. 3-4.)

In view of this claim interpretation we do not find that the Examiner has provided sufficient evidence in the prior art of first and second coated pellets such that each of the first coated pellets is substantially the same size as each of said second coated pellets. Stoll in Figure 7 shows a structure having at least two types of pellets where the first and second coating thicknesses differ. Figure 7 does not disclose, however, first and second coated pellets having substantially the same size overall. The microcapsules may have different wall thicknesses. (Stoll, col. 13, ll. 18-22.) The Examiner points to no other disclosure in Stoll which would support that the first and second coated pellets are substantially the same size.

In view of the above, the anticipation rejection is reversed.

2. Claims 5, 11, 17, 19-23 stand rejected under 35 U.S.C. § 103(a) as obvious over Stoll in view of Bennett.

Stoll has been discussed above. The Examiner acknowledges that Stoll's adhesive is not described. (Ans. 5.) Therefore the Examiner relies on Bennett for teaching that adhesives for use with prosthetic devices are well known and polymers are known adhesive with curing properties (see abstract and col. 3, lines 12-35). (Ans. 5.)

The Examiner concludes that:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the adhesive of Stoll with the claimed properties such as polymers because Bennett et al. teaches that they can be used with a variety of surgical devices. Stoll also does not specify that a plurality of sublayers on the micro-spheres. It would have been obvious to one having ordinary skill I [sic] the art at the time the invention was made to add a plurality of sublayers because Stoll does note that a plurality of layers are contemplated (see figure 5) in order to vary the degradation and release rate of the therapeutic compositions.

(Ans. 5.)

We find that Bennett fails to overcome the deficiency of Stoll and its failure to disclose first and second coated pellets of substantially the same size. In view of the above, the obviousness rejection is reversed.

SUMMARY

The anticipation and obviousness rejections are reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

REVERSED

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